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EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,748

Applicant(s)

MACK ET AL.

Examiner

Russell S. Negin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Comments

Applicants' response of November 3, 2005 is acknowledged and entered. Claims 1-64 have been cancelled and replaced with new claims 65-78. Just as in the previous action, the double patenting status of the new claims did not change. Thus, claims 65-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent Number 6,420,108 because a terminal disclaimer has not been filed.

Claim Rejections - 35 USC § 112

The previous 35 U.S.C. 112 rejections have been withdrawn and replaced with the following rejections.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 68 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In this case, the normalization operation suggested as a step of claim 68 is not supported in the original disclosure. Since no normalization operation is performed in the original disclosure of the invention, the normalization of data as dictated by the specification is considered NEW MATTER. Therefore, claim 68 is rejected.

Prior Art Rejections

The previous prior art rejections have been withdrawn and replaced with the following prior art rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65-67 and 69-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhao et al. [Gene, 1995, volume 156, pp. 207-213].

Claims 65-67 and 69-72 state the following:

65. (New) A method for displaying information for at least one expression level on a computer aided display, the method comprising:
obtaining expression level data associated with an expressed sequence from at least two samples;
generating numerical values for the expression level data for displaying on the computer aided display with at least two axes that respectively correspond to the expression level data obtained from the at least two samples;
placing at least one mark on the computer aided display at a position relative to the at least two axes in accordance with the numerical values;
receiving a selection of the mark from a user;
sending an inquiry related to the expressed sequence to a database over a communication network;

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receiving information related to the expressed sequence from the database over the communication network in response to the inquiry; and
displaying the received information related to the 'expressed sequence from the database on the computer aided display in response to the selection.

66. (New) The method of claim 65 wherein a shape of the mark is associated with the expressed sequence.

67. (New) The method of claim 65 wherein the expression level data comprise hybridization intensities of the at least two samples.

69. (New) The method of claim 65 wherein the communication network is the Internet.

70. (New) The method of claim 65 wherein:
the at least two axes comprise a horizontal axis and a vertical axis; and
the horizontal axis and the vertical axis share an origin.

71. (New) The method of claim 70 wherein a first distance of the mark from the origin relative to the horizontal axis is in accordance with at least a first value of the numerical values for a first sample of the at least two samples, and a second distance of the mark from the origin relative to the vertical axis is in accordance with at least a second value of the numerical values for a second sample of the at least two samples.

72. (New) The method of claim 65 wherein the database is related to a GenBank website.

78. (New) A computer-readable medium including instructions for displaying information for at least one expression level on a computer aided display comprising:
one or more instructions for obtaining expression level data associated with an expressed sequence from at least two samples;
one or more instructions for generating numerical values for the expression level data for displaying on the computer aided display with at least two axes that respectively correspond to the expression level data obtained from the at least two samples;
one or more instructions for placing at least one mark on the computer aided display at a position relative to the at least two axes in accordance with the numerical values;
one or more instructions for receiving a selection of the mark from a user;
one or more instructions for sending an inquiry related to the expressed sequence to a database over a communication network;
one or more instructions for receiving information related to the expressed sequence from the database over the communication network in response to the inquiry; and
one or more instructions for displaying the received information related to the

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expressed sequence from the database on the computer aided display in response to the selection.

The preamble of claim 65 is anticipated by the first phrase in the abstract of Zhao et al., who state, "In order to analyze the expression profiles of a large number of genes..." In addition, Figure 1 of Zhao et al. illustrates a picture of a computer used to display the results.

Figure 3 and its caption (in Zhao et al.) anticipate the first four steps of Claim 65. There are several sources of the samples of cDNAs, including fetal brain and adult liver of humans. Figure 3 also plots the expression levels on a two dimensional plot illustrating expression level of the two respective samples- one on each axis. There is at least one mark on this plot relative to the two axes in accordance with the numerical values, and the user (in this case Zhao et al.) selects a circular marker.

The fifth through seventh steps of the instant application's Claim 65 are anticipated in page 208 in Zhao et al. (lines 34-37), which states, "The sequence data were compared with those in GenBank DNA Nucleotide Sequence Database (Release 78) by the BLASTN program..." Thus the sequence in question is sent over a communication network (i.e. to GenBank), and then received from GenBank and BLASTN as a displayed result (see Figure 1, page 209). Since GenBank may be used as an internet based tool, claims 69 and 72 are also anticipated. The plots in Figure 3 have a horizontal axis, a vertical axis which share an origin; this anticipates claims 70 and 71.

Claim 78 of the instant application is rejected for the same reasons as described above except that it requires a computer readable medium to conduct the claim. On page 211, column 2, lines 3-7 of Zhao et al., they state, "The expression profiles of the remaining 2505 clones were illustrated in logarithmic graphs (Fig. 3) by spotting their PSL scores in two tissues with Microsoft Excel (Microsoft) on a MacIntosh personal computer." The fact that these steps are carried out on a personal computer inherently requires that there be computer readable medium supporting the operation of said Macintosh personal computer. Claim 78 is therefore rejected.

Claims 66-67 of the instant application are also anticipated by Zhao et al., Figure 3, which shows a circular shape of a mark corresponding to the expressed sequence. The expression profile of Figure 3 represents hybridization intensities, and thus, anticipates Claim 67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73-75 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. [Gene, volume 156, 1995, pp. 207-213] in view of Burks et al., [Methods in Enzymology, volume 183, 1990, pp. 3-22].

Claims 73-75 and 77 state the following:

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73. (New) The method of claim 72 wherein the displayed information on the computer aided display comprises identification information associated with the mark.

74. (New) The method of claim 72 wherein the displayed information on the computer aided display comprises a description associated with the mark.

75. (New) The method of claim 72 wherein the displayed information on the computer aided display comprises GenBank information associated with the mark.

77. (New) A method for displaying information for at least one expression level on a computer aided display, the method comprising:
obtaining expression level data associated with an expressed sequence from at least two samples;
generating numerical values for the expression level data for displaying on the computer aided display with at least two axes that respectively correspond to the expression level data obtained from the at least two samples;
placing at least one mark on the computer aided display at a position relative to the at least two axes in accordance with the numerical values;
receiving a selection of the mark from a user;
determining whether an internal database contains the information related to the expressed sequence;
if the internal database is determined to contain the information related to the expressed sequence,
obtaining the information related to the expressed sequence from the internal database;
and
displaying the received information related to the expressed sequence from the internal database on the computer aided display in response to the selection;
if the internal database is determined not to contain the information related to the expressed sequence,
sending an inquiry related to the expressed sequence to an external database over a communication network;
receiving information related to the expressed sequence from the external database over the communication network in response to the inquiry; and
displaying the received information related to the expressed sequence from the external database on the computer aided display in response to the selection.

The preamble and first four steps of claim 77 are described by Zhao et al. in the same manner that Zhao et al. anticipated similar wordings of Claim 65 (i.e. Figure 3 of Zhao et al. describes the plotting of the at least two samples). However, Zhao et al. do

not elaborate on the uses of external and internal databases or identification information associated with marks. For this purpose, the reference of Burks et al. is employed.

Claims 73-75 are described by Figure 1 of Burks et al. This figure illustrates identification information associated with the mark, description associated with the mark, and GenBank information associated with the mark (for the sample gene shown in the illustration).

The fifth and sixth steps of claim 77 are essentially an IF-THEN dialog of how to process the expression data. If the internal database contains relevant information, use the internal database; otherwise use the external database. Pages 17-18 of Burks et al. describe the same conditions from GenBank. Under "Access to GenBank Data," Burks et al. describe that internal data such as Magnetic Tape and Floppy diskettes can be used, and alternatively an external "Dial-Up Online Service" can be used. This description satisfies the requirement listed in claim 77 of the instant application.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of Zhao et al., using the GenBank software of Burks et al. in order to result in the practice of the instantly claimed invention because the method steps described by Zhao et al. require a database such as GenBank to complete the analysis.

Moreover, one of ordinary skill in the art would have been motivated to apply a third axis to Zhao et al. display format in order to further compare the expression level in a third sample. It would have been advantageous to use a 3D format to compare three samples at the same time so that comparisons would be visually easier to interpret and

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would be performed simultaneously. It would have been *prima facie* obvious to apply a third axis to Zhao et al's display format in order to analyze more information at the same time. Thus, Claim 76 is also rejected under 35 U.S.C. 103.

Conclusion

No Claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Ardin Marschel, Ph.D., Supervisory Patent Examiner, can be reached at (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

-RSN 12/22/05

RRM 12/22/05

John S. Brusca 22 December 2005
JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER